ORIGINAL RESEARCH: SHORT REPORT

Sunscreen compliance with regional clinical practice guidelines and product labelling standards in New Zealand

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ABSTRACT

INTRODUCTION: For general practitioners, practice nurses and community pharmacists in New Zealand, a core duty is to educate patients about sun protection. We aimed to evaluate compliance of locally available sunscreens with regional clinical practice guidelines and sunscreen labelling standards, to assist clinicians in advising consumers on sunscreen selection.

METHODS: We audited all sunscreens available at two Auckland stores for three New Zealand sunscreen retailers. We then assessed compliance with accepted regional clinical practice guidelines for sun protection from the New Zealand Guidelines Group. We further assessed compliance with regional Australia/New Zealand consumer standards for sunscreen labelling.

RESULTS: All sunscreens satisfied clinical guidelines for broad-spectrum protection, and 99% of sunscreens met or exceeded clinical guidelines for minimal Sun Protection Factor. Compliance with regional standardized labelling guidelines is voluntary in New Zealand and 27% of audited sunscreens were not fully compliant with SPF labelling standards.

DISCUSSION: Sunscreens were generally compliant with clinical guidelines for minimal sun protection. However there was substantial noncompliance with regional recommendations for standardized sunscreen labelling. Primary health care clinicians should be aware that this labelling noncompliance may mislead patients into thinking some sunscreens offer more sun protection than they do. Mandatory compliance with the latest regional labelling standards would simplify sunscreen selection by New Zealand consumers.

KEYWORDS: Sunscreen; Sun Protection Factor; SPF; Skin Neoplasms; Melanoma; Skin Cancer Prevention

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Introduction

Skin cancer is a substantial burden to the New Zealand population and health care system. In New Zealand, melanoma is the only skin cancer mandatorily notified under the Cancer Registration Act 1993, which precludes accurate assessment of overall skin cancer incidence. However, New Zealand has one of the highest melanoma rates in the world.¹ Melanoma was the fourth most common cancer here in 2011, accounting for 4% of all cancer deaths.² For male patients aged 25–44 years, melanoma is one of the most commonly registered cancers.² The direct treatment costs of squamous cell and basal cell carcinomas in New Zealand was estimated at around \$57 million in 2009.¹

The regular use of sunscreen, along with other sun protection strategies, reduces the incidence of skin cancers.^{3–6} Not surprisingly, it follows that encouragement of effective sunscreen utilisation is an important component of preventive health protection strategies for general

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³ University of Auckland School of Medicine, Auckland, New Zealand practitioners, practice nurses and community pharmacists in New Zealand. Patient compliance with sunscreen use has been shown to significantly improve over a period of several years following personal consultation in primary care.⁷

There are numerous different sunscreen formulations that either reflect or absorb ultraviolet (UV) radiation. A principle measure of sunscreen performance is the sun protection factor (SPF), defined as the ratio between the time it takes to gain slight sunburn with and without sunscreen. This means that SPF-10 sunscreen allows one to remain in the sun ten times longer than their baseline before getting sunburned.⁸

Permanent skin damage is commonly attributed to the UVA and UVB components of the sun's spectrum.9 Research indicates that UV-induced free radicals elicit genetic mutations, including loss of tumour suppressor activity.¹⁰ UVB was initially thought to be more important in sun-induced skin damage because sunburns, as a measure of excess sun exposure, have been identified as a risk factor for skin cancer^{11,12} and sunburns are primarily caused by UVB radiation (280-320 nm). However UVA, which penetrates deeper into the skin, also plays a potential role in melanoma pathogenesis by causing long-term cellular damage.13 Accordingly, contemporary 'broad-spectrum' sunscreens are advocated to provide both UVA and UVB protection.

Two sets of regional guidelines are particularly relevant to education on effective sunscreen utilisation for New Zealand sunscreen consumers. These include the clinical practice recommendations on sun protection published by the New Zealand Guideline Group (NZGG) and supported by the New Zealand Ministry of Health,¹⁴ and the standardized sunscreen labelling recommendations of the latest Australian and New Zealand Sunscreen Standard (AS/NZS 2604:2012) and regulated by the Australian Therapeutic Goods Administration.¹⁵

The clinical practice recommendations on sun protection published by the NZGG reflect the consensus recommendations of the Cancer

WHAT GAP THIS FILLS

What we already know: The regular use of sunscreen, along with other sun protection strategies, reduces the incidence of skin cancers. Two sets of regional guidelines relevant to sunscreen selection include the New Zealand Guideline Group's clinical practice recommendations on sun protection, and the Australian and New Zealand Sunscreen Standard (AS/NZS 2604:2012).

What this study adds: Sunscreens evaluated at six retail stores in Auckland were generally compliant with clinical practice guidelines for sun protection. However 27% of audited sunscreens were not compliant with regional labelling standards and this noncompliance may mislead patients into thinking some sunscreens offer more protection than they do.

Council Australia, the Cancer Society of New Zealand and the Health Sponsorship Council of New Zealand.¹⁴ A summary of its key recommendations is provided in Table 1. Notable to the current study's evaluation is recommendation for sunscreens with SPF 30 or higher providing broad spectrum UV protection.

The Australian and New Zealand (ANZ) Sunscreen Standard is intended to ensure that claims marketed by sunscreen manufacturers are true, valid and not misleading.¹⁵ Standardized labelling recommendations of the sunscreen standard can be helpful in fairly assessing sunscreen claims made by manufacturers. A summary of its key recommendations according to the latest standard is provided in Table 2. Importantly, manufacturer adherence to these standards is currently voluntary in New Zealand.¹⁶ This contrasts with Australia, where standards are enforced for primary therapeutic sunscreens by the Australian Register of Therapeutic Goods.¹⁵

To assist general practitioners, practice nurses and community pharmacists with advising consumers on sunscreen selection in New Zealand, we audited all sunscreens available in three sunscreen retail chains and evaluated their compliance with regional clinical practice guidelines and regional sunscreen labelling standards as outlined in Tables 1 & 2.

Methods

We audited all sunscreen products for sale at six different major retail stores across Auckland between October 2014 and January 2015. Two stores each were sampled from the three retail chains 'Countdown,' 'Life Pharmacy' and 'The Warehouse.' For each sunscreen product, data recorded included manufacturer's brand name, SPF, UVA and UVB versus broad spectrum protection, water resistance claims, formulation, retail price and unit volume. Sunscreen products were then evaluated according to congruence with regional clinical practice guidelines and labelling standards as summarised in Tables 1 & 2.

Results

In total, 108 different products were analysed. This included sunscreens from 15 different brands: Aquasun, Banana Boat, Botanica, Cancer Society, Coppertone, Daylong, Ego Sunsense, Garnier Ambre, Hamilton, Invisible Zinc,

Table 1. New Zealand Guideline Group: Summary of key sun protection recommendations $^{\rm 14}$

- 1. Sun exposure should be limited during peak UV radiation periods (*i.e.*, 11am to 4pm during daylight savings months), and completely avoided for infants under the age of six months
- 2. Sunscreens should be applied to sun-exposed skin
- 3. Sunscreens should be rated SPF 30 or higher
- 4. Sunscreen should offer 'Broad Spectrum' (UVA and UVB) protection
- 5. Sunscreens should be applied at least 20 min before going outside and reapplied every 2 h while exposed

Table 2. Australia/New Zealand Sunscreen Standard 2012 (AS/NZS 2604:2012): Summary of key regulatory guidelines¹⁵

- 1. SPF claims should be limited to 4, 6, 8, 10, 15, 20, 25, 30, 40, 50, and 50+ based on standardized testing, with a maximum permissible SPF claim of '50+'
- 2. SPF categorization is standardized as 'Low' for SPF 4–10, 'Medium' for SPF 15–25, 'High' for SPF 30–50, and 'Very High' for SPF 50+
- 3. Broad spectrum protection is mandatory for all primary sunscreens
- 4. The allowable claims for water resistance for sunscreens with SPF less than 30 is limited to up to 2 h, while sunscreens with SPF 30 or above is limited to up to 4 h
- 5. The terms 'sunblock,' 'waterproof,' and 'sweat proof' are deemed generally misleading and are not permitted

Neutrogena, Nivea Sun, Ozone, Reef, and Smart 365 (listed alphabetically). Four formulations were available: lotion, lotion spray, roll-on, and spray or mist. Unit sizes ranged from 30 to 500 ml. Thirty (27%) of the sunscreens evaluated varied only in unit size or formulation but not ingredients or concentration of active ingredients. Sixty products were completely unique. Sixty three products (58%) were only found in one of the retail chains audited.

The advertised SPF ranged from 15 to 85+. Ten sunscreens (9%) were labelled with an SPF between 60 and 85+. One sunscreen advertised an SPF of 15, and all others (99%) were SPF 30 or greater.

Eighteen sunscreens labelled as 'SPF 30' or 'SPF 30+' were marketed as providing 'very high' sun protection. All sunscreens evaluated advertised broad-spectrum protection. More than half of the sunscreens (57%) advertised up to four hours water resistance and 29% claimed water resistance ranging from 80 to 180 min. Each of these claims was congruent with standards according to SPF rating. The remaining (14%) made no claims regarding water resistance. No claims of 'sunblock,' 'waterproof,' or 'sweat proof' were identified.

Discussion

Sun exposure and the accompanying incidence of sunburn increase the risk of melanoma and non-melanoma skin cancer.^{11,12,14} As advocated by the New Zealand Ministry of Health, patients should be advised to avoid sunburns and to use sunscreens along with physical methods for UV protection.¹⁴

We found it relatively easy for consumers to select sunscreens meeting the minimum SPF 30 recommendation according to the ANZ Sunscreen Standard. Of the 108 products audited at 6 stores, only one had an SPF less than 30.

Our audit found that SPF reporting did not adhere to the latest ANZ Sunscreen Standard 27% of the time. This sunscreen standard, known as AS/NZS 2604:2012¹⁵ was introduced in 2012 to regulate and standardize the way the suppliers

test, define and label SPF performance of their products, and to improve consumer evaluation and confidence.¹⁵ Adherence to this standard is currently voluntary in New Zealand because sunscreens are classified as loosely regulated cosmetics in this country, whereas in Australia primary sunscreens are legislated by the Therapeutic Goods Association.¹⁶

Products not adhering to labelling standards fell into two categories. First, 18 sunscreens labelled as 'SPF 30' or 'SPF 30+' were marketed as providing 'very high' sun protection, but the qualification of 'very high' sun protection is reserved only for sunscreens with SPF 50+ according to the latest standards. Second, 10 sunscreens advertised an SPF greater than 50+, thereby breaching the upper limit of SPF labelling permitted by the latest standards. Equivocal additional sun protection benefit has been shown beyond the SPF50+ stratification level, and this upper limit in SPF labelling is one that has been accepted internationally.16 This non-compliance with standardized labelling may mislead patients into thinking these sunscreens offer more sun protection than they do.

A reassuring finding of this study is that all sunscreens evaluated meet regional clinical practice recommendations for broad-spectrum UVA plus UVB protection, standardized water resistance claims, and avoidance of misleading terms such as 'waterproof,' 'sunblock,' and 'sweat-proof.'

This study was limited to sunscreens sold by six major retail chain locations in Auckland and thus does not include every sunscreen marketed throughout all regions of New Zealand. However, we feel that the results of this study are relevant throughout New Zealand because the diversity of product selection available in the Auckland market and sampled in this study is assumed to encompass the majority of the range of sunscreen products available throughout New Zealand.

In summary, sunscreens audited were generally compliant with regional clinical guidelines for minimal sun protection and broad spectrum coverage. However there was substantial noncompliance with regional recommendations for standardized sunscreen labelling. Primary health care practitioners should be aware that this labelling noncompliance may be misleading patients into thinking some sunscreens offer more sun protection than they do. Further consideration of mandatory compliance with regional sunscreen standards within New Zealand may be warranted.

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